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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/807,868

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Richard Leske

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JONDLE & ASSOCIATES P.C.
9085 EAST MINERAL CIRCLE
SUITE 200
CENTENNIAL, CO 80112

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/807,868

Applicant(s)

LESKE ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 and 11-23 is/are allowed.
- 6) ☒ Claim(s) 8-10 and 24-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/22/04, 4/8/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 4, 5 and 27 are objected to because of the following informalities:

(a) claim 4 is objected to for the omission of "A" before "protoplasts produced from..." and the use of "protoplasts" because only a single invention can be claimed.

These objections can be obviated by amending the claim to read – A protoplast – before "produced from...".

(b) claim 5 is objected to for the phrase "...the tissue culture are from..." . This phrase appears to unduly limit the invention to a first generation tissue culture. It is recommended that Applicant amend the claim to read -- ... the tissue culture are produced from... -- .

(c) claim 27 is objected to because "by a transgene" lacks antecedent basis.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-10 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-10 are broadly drawn to hybrid cotton plants, however, the specification does not describe the other cotton plant or plants that are to be crossed with DP 543 BGII/RR nor is there a description of their genetic, morphological, and/or physiological background. It is known in the art that any plant produced from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci, therefore, the hybrid plant will contain 50% of the alleles from the DP 543 BGII/RR cotton plant and 50% of the alleles from the other uncharacterized cotton plant. The limitation "a part thereof" in claim 9 reads on an additional generation of outcrossing to a non-DP 543 BGII/RR cotton parent so that seed with as little as 25% of the DP 543 BGII/RR alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is produced from crossing DP 543 BGII/RR with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids.

Claims 24-28 are broadly drawn to a method of introducing a desired trait into cotton cultivar DP 543 BGII/RR by crossing said cultivar with any cotton cultivar and backcrossing the resulting progeny to said cultivar and plants produced from said method.

The specification does not provide a written description of the other cotton cultivar in terms of its genetic, morphological, and/or physiological characteristics nor is there any evidence provided in the specification describing any cotton plants having

male sterility, herbicide resistance, and disease resistance that are crossed with DP 543 BGII/RR. There is no explanation regarding the "5% significance level" in terms as how it is measured, nor is there any written description with regards to "environmental conditions".

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern US Patent 5,850,009, column 4, lines 41-46); therefore, Applicant has not described the myriad of different hybrids that may be produced from the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and

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that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus”. Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed hybrid cotton plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the invention as broadly claimed. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

4. Claims 8-10 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 8-10 are broadly drawn to hybrid cotton plants, however, the specification does not give any guidance as to the other cotton plant or plants that are to be crossed with DP 543 BGII/RR nor is there any guidance as to their genetic, morphological, and/or physiological background. It is known in the art that any plant produced from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci, therefore, the hybrid plant will contain 50% of the alleles from the DP 543 BGII/RR cotton plant and 50% of the alleles from the other uncharacterized cotton plant. The limitation "a part thereof" in claim 9 reads on an additional generation of outcrossing to a non-DP 543 BGII/RR cotton parent so that seed with as little as 25% of the DP 543 BGII/RR alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not taught in the specification. Since the claimed invention is derived from crossing DP 543 BGII/RR with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids in terms of

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their traits, or provide any guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

Claims 24-28 are broadly drawn to the crossing of any cotton plant in the method of introducing a desired trait into cotton cultivar DP 543 BGII/RR and any plants produced by said method.

The specification lacks the presence of working examples of the invention with regards to the cotton cultivar used in the cross and plants that exhibit the desired plants as claimed. The specification does not teach any cotton plant having any of the claimed desired traits wherein said plant is crossed with cotton cultivar DP 543 BGII/RR in terms of its genetic, morphological, and/or physiological characteristics. The specification does not teach the species of cotton plant used in the cross with DP 543 BGII/RR. Fryxell (*In Cotton*, Agronomy Monograph 24, p. 27-57, 1984) teaches that the crossing of diploid *G. sturtianum* with the tetraploid *G. hirsutum* produces sterile triploid hybrids (see page 54, third paragraph). The specification does not teach how to measure the “5% significance level” nor does it teach the “environmental conditions” used to determine the plants produced by the claimed method. Since the claimed invention utilizes the crossing of DP 543 BGII/RR with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different “other” parents and the specification does not describe these hundreds of hybrids in terms of their traits, or provide any guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention without undue experimentation.

Breeding for desired traits is unpredictable. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46).

For example, Fryxell teaches that most cotton plants in the cotton germplasm collection "behave photoperiodically and fail to flower under the long-day regime of the temperate-zone growing season" thus making them "not directly available for crossing and incorporation into cotton breeding programs" (see page 53, first paragraph). Fryxell also teaches even though backcrossing procedures for a desired trait is relatively straightforward, the methods are not simple if "a gene is being transferred across a ploidy level difference" (see page 54, first paragraph). Mishra et al (Plant Cell Tissue and Organ Culture 73: 21-35, 2003) teach that linkage drag is a concern during introgression of transgenes into elite cultivars (see page 22, second column, lines 6-13 and page 34, second column, lines 21-25). The specification teaches, "The breeder can theoretically generate billions of different genetic combinations" by crossing two or more parental lines and that "The breeder has no direct control over which genetic combinations will arise..." (see page 3, paragraph 0012). Furthermore, the specification teaches that "lines which are developed are unpredictable" and that "This unpredictability is because the breeder's selection occurs in unique environments, with

no control at the DNA level...with millions of different possible genetic combinations being generated" (see page 4, paragraph 0013).

Furthermore, the use of backcrossing in plant breeding is unpredictable. Zeven et al (Euphytica 32: 319-327, 1983) teach that linkage drag is very common in backcross breeding (see page 325-327). Young et al (Theor. Appl. Genet. 77: 353-359, 1989) teach that "backcross breeding is only moderately effective in reducing linkage drag around gene targets" (see page 357, first column, second full paragraph). Ragot et al (Techniques et utilisations des marqueurs moleculaires (France), pp. 45-56, 1994) teach that "full recovery of recurrent parent genotype is usually not achieved through classical backcrossing, which may result in deleterious agronomic effects" (see page 46, first paragraph); therefore it is unpredictable which useful traits will be retained.

Neither the instant specification nor the prior art provides evidence that such linkage drag is not common in cotton breeding materials, such that one or more genes can be transferred from one genetic background to another, wherein the resultant cotton progeny would express the desired trait and maintain all of the other desirable genes and traits of cotton cultivar DP 543 BGII/RR.

Given the lack of guidance in Applicant's specification regarding a multitude of non-exemplified hybrids, single gene conversions, the unpredictability of transferring said genes, and the breadth of the claims, one skilled in the art would not be able to make and/or use the invention claimed without undue experimentations.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace et al (Crop Sci. 42: 2216-2217, 2002).

The claims read on F2 progeny, including segregating progeny with 100% of non-DP 543 BGII/RR alleles; therefore, the claim reads on any cotton plant or seed with any alleles at any locus. The claimed method of making the plant or seed would not confer a unique property to the resultant non-DP 543 BGII/RR cotton plant or seed.

Wallace et al teach a cotton plant and seeds thereof (see page 2216, second column to page 2217, end of the first column).

Wallace et al do not teach cotton plants or seeds derived from the cross of cotton cultivar DP 543 BGII/RR with another cotton plant.

The cotton plant taught by the prior art differs from the claimed cotton plant only in their method of making, namely by the use of different parental material in the prior

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art. However, the method of making the claimed cotton plant would not distinguish it from the prior art cotton plant. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

7. Claims 1-7 and 11-28 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified cotton plant which possesses a unique genetic complement and unique collection of traits as that of cotton cultivar DP 543 BGII/RR, or methods of using said cotton cultivar.

8. Claims 8-10 and 24-28 are rejected.

9. Claims 1-7 and 11-23 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

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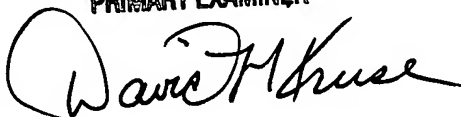
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

April 22, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written over a circular stamp or mark.